

Highlights of Manual 3035: Working Safely with Hazardous Biological Materials

Read the full Manual Chapter 3035: Working Safely with Hazardous Biological Materials
<http://www1.od.nih.gov/oma/manualchapters/intramural/3035/>
(NIH access only)

Established under this chapter is the National Institutes of Health (NIH) policy governing the conduct of work with hazardous biological materials in the research environment, including recombinant DNA materials, toxins and human pathogens classified at Biosafety Level 2 (BL-2) and higher and Select Agents as defined in 42 CFR 72.6, Additional Requirements for Facilities Transferring or Receiving Select Agents. All work with hazardous biological materials will be conducted in compliance with the publication, Biosafety in Microbiological and Biomedical Laboratories. The policy for working with bloodborne pathogens is set forth in the NIH Bloodborne Pathogen Exposure Control Plan for Non-Hospital Personnel.

Laboratories where work at BSL-2 and higher is conducted, shall be posted with signage indicating the assigned biosafety level, biological material(s) in use, special procedures or precautions for entry, name of the Principal Investigator with work and emergency phone numbers. These laboratories will be inspected by DOHS staff to ensure that the facility is operating properly for the biosafety level and that appropriate practices and procedures are observed. Follow-up inspections shall be conducted.

Responsibilities:

NIH Institutional Biosafety Committee (IBC)

The IBC, whose functions are defined under the NIH Guidelines for Research Involving Recombinant DNA Molecules (Guidelines), reviews and approves research protocols involving the use of potentially infectious materials.

Division of Occupational Health and Safety (DOHS)

The DOHS is responsible for managing biological safety at the NIH and provides a broad range of support services, consultation and assistance. The Division of Occupational Health and Safety provides training support to help supervisors fulfill the training requirements stated in 29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogens. Training classes which address the recognition and control of common biological, chemical and physical hazards found in NIH laboratories, as well as safe work practices with human and nonhuman primate retroviruses and other bloodborne pathogens are routinely presented.

Supervisor

Employee training is an important component in the safe conduct of work with biological materials. Providing the initial training and annual retraining of personnel, as required under 29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogens and subsequent health standards, is the responsibility of the immediate supervisor. Supervisors are also accountable for ensuring that their employees are advised of the potential hazards associated with infectious agents and the proper use of laboratory equipment, including containment devices.

Principal Investigator (PI)

Principal Investigators working with recombinant DNA shall complete and submit to the IBC, NIH form 2690 Registration Document for Recombinant DNA Experiments, prior to the initiation of any experiment which requires approval under the Guidelines. The PI is responsible for compliance with the Guidelines in the conduct of recombinant DNA research and ensuring that appropriate reviews and approvals are obtained prior to initiation of experiments.

Principal Investigators are responsible for submitting the form, Registration of materials (Potentially) Infectious for Humans (DOHS 1/97), for all work involving human pathogens or human blood, tissues and body fluids including primary human cell cultures.

Principal Investigators who wish to transfer or receive a Select Agent (virus, bacterium, fungus, rickettsia or toxin) or associated genetic elements (shown to produce or encode for a factor associated with disease) as listed in Appendix A, 42 CFR Part 72.6 must contact the NIH Biosafety Officer (DOHS, SOSB) for assistance and approval.

Principal Investigators operating or working in a BSL-3 laboratory must secure all potentially infectious materials prior to allowing entry of support personnel such as maintenance employees. All laboratory components (sinks, countertops, etc.) and equipment scheduled for repair or servicing will be thoroughly decontaminated by research personnel prior to initiation of the work. A staff member familiar with the operation of the laboratory shall be present during normal working hours whenever maintenance/repair work is being conducted.

In the event of an after hours emergency in a BSL-3 laboratory, the PI will be contacted at home prior to maintenance personnel entering the area. The information posted on the laboratory door sign must be kept current to facilitate this response.